AUG 13 2008

VI. Summary of Safety and Effectiveness

Submitter's name, address, telephone number and contact person:

Bioplate, Inc.
3643 Lenawee Avenue
Los Angeles, CA, 90016
(310) 815-2100
(310) 815-2126 (fax)

Contact Person: Jesus Farinas

Trade name of Device:

Modified design of the Bioplate ZIP® Craniotomy Fixation System (K013050, K020088)

Common Name:

Bone Fixation Plates

Device Classification:

Class 2, 21 CFR 882-5330
GXN

Predicate Devices:

(1) Bioplate, Inc.
The Bioplate ZIP® Craniotomy Fixation System (K070901)

(2.) Bioplate, Inc.
The Bioplate ZIP® Craniotomy Fixation System (K013050)

(3.) Bioplate, Inc.
Device Modification of the Bioplate ZIP® Craniotomy Fixation System (K020088)

Description of the Device:

The Bioplate ZIP® Craniotomy Fixation System consists of two circular caps, in a parallel configuration that is connected by an internal, serrated post. The devices will be available in several sizes with cap diameters in the range of 12mm to 20mm to be used for varying cranial closure techniques. The device will be packaged and provided Sterile (by gamma radiation)

Intended Use of the Device:

The Bioplate ZIP® Craniotomy Fixation System is intended to reattach a cranial bone flap to the surrounding cranium after a craniotomy procedure. The device is used to align and stabilize bony tissue while normal healing occurs. Each device is intended for single use only and may be combined only with other titanium and titanium alloy implants.

Comparison of the device's technological characteristics with those of the predicate devices

All of the technical characteristics are substantially equivalent to the corresponding characteristics of the predicate devices, and any minor differences raise no new issues of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 2008

Bioplate, Inc.
% Mr. Jesus T. Farinas
Director, QA/RA
3643 Lenawee Avenue
Los Angeles, California 90016-4310

Re: K082175
Trade/Device Name: Bioplate ZIP® Craniotomy Fixation System
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed nonalterable cranioplasty plate
Regulatory Class: Class II
Product Code: GXN
Dated: July 31, 2008
Received: August 1, 2008

Dear Mr. Farinas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use

510(k) Number (if known) **K082175**

Device Name: Modified plate design for Bioplate ZIP® Craniotomy Fixation System.

Indication for Use:

The Sterile Bioplate ZIP® Craniotomy Fixation System is intended to reattach a cranial bone flap to the surrounding cranium after a craniotomy procedure. The device is used to align and stabilize bony tissue while normal healing occurs. Each device is intended for single use only and may be combined only with other titanium and titanium alloy implants.

Prescription Use ____X_____ AND/OR Over-The Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of the CDRH, Office of Evaluation (ODE)

Barbara Bucelli MD for MXA

(Division Sign-Off) Page 1 of ____

Division of General, Restorative,
and Neurological Devices

510(k) Number K082175